

# CLAIMS

1. An *in vitro* method of functionally determining at physiological conditions deficiencies in the lectin pathway of the complement system, the method comprising the steps of
  - (a) providing a sample of mammalian blood, serum, plasma, or another body fluid;
  - (b) preventing in the sample the activation of the classical pathway by contacting the sample with an inhibitor of a molecule of the C1 complex of the complement system;
  - (d) preventing in the sample the activation of the alternative pathway;
  - (d) activating the lectin pathway in the sample; and
  - (e) determining in the sample any activation of the autologous C5b-9 complex.
2. The method as in claim 1, wherein in (b) the inhibitor of a molecule of the C1 complex is an antibody against C1q.
3. The method as in claim 1, wherein in (b) the inhibitor of a molecule of the C1 complex is a peptide inhibiting C1q.
4. The method as in claim 1, wherein in (b) the inhibitor of a molecule of the C1 complex is a inhibitory C1q-binding protein.
5. The method as in claim 1, wherein in (b) the inhibitor of a molecule of the C1 complex is a small inhibitory C1q-binding molecule.
- ~~6. The method as in claim 1, wherein in (b) the inhibitor of a molecule of the C1 complex is an antibody directed against C1r or C1s.~~
7. The method as in claim 1, wherein in (b) the inhibitor of a molecule of the C1 complex is a peptide inhibitor of C1r or C1s.

8. The method as in claim 1, wherein in (b) the inhibitor of a molecule of the C1 complex is a protease inhibitor of C1r or C1s.

9. The method as in claim 1, wherein in (c) the  
5 activation of the alternative pathway is prevented by dilution of the sample.

10. The method as in claim 1, wherein in (c) the activation of the alternative pathway is prevented by contacting the sample with a protease inhibitor of factor D.

11. The method as in claim 1, wherein in (c) the  
10 activation of the alternative pathway is prevented by contacting the sample with an antibody directed against factor D.

12. The method as in claim 1, wherein in (d) the  
15 lectin pathway is activated by contacting the sample with a MBL-binding carbohydrate.

13. The method as in claim 12, wherein the MBL-binding carbohydrate is a mannan.

14. The method as in claim 1, wherein in (d) the  
20 lectin pathway is activated by contacting the sample with a ficolin-binding carbohydrate.

15. The method as in claim 1, wherein in (e) any  
activation of the autologous C5b-9 complex is determined by  
contacting the sample with antibodies against the  
25 autologous C5b-9 complex.

16. A kit for functionally determining in a body fluid from a mammal deficiencies in the lectin pathway of the complement system, which kit comprises the separate items

- 30 (a) an inert carrier and a substance activating the lectin pathway;  
(b) a diluent comprising an inhibitor of a molecule of the C1 complex; and  
(j) an antibody against the autologous C5b-9 complex.

17. The kit as in claim 16, wherein in item (a) the activating substance is a MBL-binding carbohydrate.

18. The kit as in claim 17, wherein the MBL-binding carbohydrate is a mannan.

5        19. The kit as in claim 16, wherein in item (a) the activating substance is a ficolin-binding carbohydrate.

20. The kit as in any of claims 16-19, wherein in item (a) the activating substance is coated onto the carrier.

10        21. The kit as in claim 16, wherein in item (b) the inhibitor of a molecule of the C1 complex is an antibody against Clq.

22. The kit as in claim 16, wherein in item (b) the inhibitor of a molecule of the C1 complex is a peptide  
15        inhibiting Clq.

23. The kit as in claim 16, wherein in item (b) the inhibitor of a molecule of the C1 complex is a inhibitory Clq-binding protein.

24. The kit as in claim 16, wherein in item (b) the  
20        inhibitor of a molecule of the C1 complex is a small inhibitory Clq-binding molecule.

25. The kit as in claim 16, wherein in item (b) the inhibitor of a molecule of the C1 complex is an antibody directed against Clr or C1s.

25        26. The kit as in claim 16, wherein in item (b) the inhibitor of a molecule of the C1 complex is a peptide inhibitor of Clr or C1s.

27. The kit as in claim 16, wherein in item (b) the inhibitor of a molecule of the C1 complex is a protease  
30        inhibitor of Clr or C1s.

28. The kit as in claim 16, wherein in item (c) the antibody is a labeled antibody.

29. The kit as in claim 16, which further comprises a labeled anti-antibody against the antibody against the  
35        autologous C5b-9 complex as a separate item (d).

30. The kit as in claim 28 or 29, wherein the label is a fluorescent label.

31. The kit as in claim 28 or 29, wherein the label is an enzyme.

5 32. The kit as in claim 16 and 31, which further comprises an enzyme substrate as a separate item (e).

33. The kit as in claim 16, which further comprises a washing solution as a separate item (f).

10 34. The kit as in claim 16, which further comprises a normal body liquid from a mammal as a separate item (g).

35. The kit as in claim 34, wherein in item (g) the normal body liquid is a normal human serum.

15 36. The kit as in claim 16, which further comprises an inactivated normal body liquid from a mammal as a separate item (h).

37. The kit as in claim 36, wherein in item (h) the inactivated normal body liquid is heat inactivated human serum.